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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,471	07/23/2003	Angel Pellicer	PELLICER1A	1686
7590 03/28/2007 BROWDY AND NEIMARK, P.L.L.C. 624 Ninth Street, N.W. Washington, DC 20001-5303			EXAMINER HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
			1643	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/28/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/625,471	<b>Applicant(s)</b> PELLICER ET AL.	
	<b>Examiner</b> Anne L. Holleran	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-18, 20, 21, 23-35 is/are pending in the application.
- 4a) Of the above claim(s) 27-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 20, 21, 23, 24, 26, 34 and 35 is/are rejected.
- 7) ☒ Claim(s) 17, 18 and 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. The amendment file 12/14/2006 is acknowledged. Claims 1-15, 19 and 22 were canceled.
2. Claims 16-18, 20, 21, 23-35 are pending. Claims 27-33, drawn to non-elected inventions, are withdrawn from consideration.

Claims 16-18, 20, 21, 23-26, 34 and 35 are examined on the merits.

***Claim Objections/Rejections Withdrawn:***

3. The objection to claims 16, 19 and 20 for depending from a claim that is withdrawn from consideration is withdrawn in view of the amendment to claim 16 and 20, and the cancellation of claim 19.

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 16, 20, 34 and 35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.
5. The rejection of claims 16, 20, 34 and 35 under 35 U.S.C. 102(b) as being anticipated by D'Adamo (D'Adamo, et al., Oncogene, 14: 1295-1305, 1997; cited in the IDS) or Miller (Miller, M.J. et al., Journal of Biological Chemistry, 272(9): 5600-5605, 1997) is withdrawn in view of the amendments to the claims.

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8. The rejection of claims 16, 20, 22-25 under 35 U.S.C. 102(a) as being anticipated by Accession No. BI837800, (NIH-Mammalian Gene Collection, 04 Oct. 2001) is withdrawn in view of the amendment to the claims.

***Claim Rejections Maintained and New Grounds of Rejection:***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 (and dependent claim 26) is indefinite because it appears to be missing a phrase such as, for example, "the abnormally truncated variant".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 16, 20, 21, 34 and 35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids that encode a polypeptide that comprises the amino acid sequence of SEQ ID NO: 2, or for nucleic acids *consisting of* nucleic acid sequences that encode SEQ ID NO: 8, or for specific nucleic acids *consisting of* the sequences of SEQ ID NOS: 5-7 and 9, 11, 13, 15, 17, 19, 21 and 23, does not

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reasonably provide enablement for nucleic acids encoding a polypeptide that is a variant of human Rgr consisting of an amino acid sequence with at least 98% sequence identity to SEQ ID NO: 2, or *comprises* the nucleic acid sequences of SEQ ID NOS: 5-7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the amendments to the claims obviate the rejection of record. This is not found persuasive because, as explained in the previous Office action, it is not clear from the specification how one of skill in the art may use nucleic acids that encode polypeptides having functional activity that is not the same as the amino acid sequence of SEQ ID NO: 2, which encodes human Rgr. In the previous Office action, the examiner noted that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein, and that the specification does not teach specific biological activities of human Rgr, and that it is unpredictable whether human Rgr exhibits exactly the same set of activities as rabbit Rgr. Therefore, the claims to nucleic acids encoding variant polypeptides of human Rgr consisting of an amino acid sequence with at least 98% sequence identity to the amino acid sequence of SEQ ID NO: 2 are not enabled by the specification because one of skill in the art would first have to establish what are the activities of human Rgr, and then to screen for the working embodiments. Without a set of activities to use in a routine assay, it would require further and undue experimentation to screen for useful variants of human Rgr protein consisting of an amino acid sequence with at least 98% sequence identity to SEQ ID NO: 2. Furthermore, the claim 16 and also claim 20 contains the recitation "consisting of an amino acid sequence with

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at least 98% identity to SEQ ID NO: 2” reads on subsequences of SEQ ID NO: 2, where the amino acid sequences of the subsequences has 98% sequence identity with SEQ ID NO: 2.

Applicants also explain that in one aspect the claims are limited to polynucleotides consisting of the nucleic acid sequence of SEQ ID NO: 5, SEQ ID NO: 6 or SEQ ID NO: 7. However, in claim 16 the claims are drawn to “isolated nuclei acid molecules comprising a nucleotide sequence...”. Therefore, the claims read on nucleic acid sequences comprising fragments of a polynucleotide encoding SEQ ID NO: 2.

11. Claims 16, 20 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to provide a description that is sufficient to support genus claims.

Applicants assert that the claim amendments obviate the rejections under 35 USC 112, first paragraph. This is not found persuasive because claim 16 continues to be drawn to “nucleic acid molecules comprising a nucleotide sequence”, and because claim 20 recites “wherein the polypeptide consists of an amino acid sequence with at least 98% sequence identity to SEQ ID NO: 2, which reads on subsequences. Claim 21 depends from claim 20, and appears to read on subsequences because it is dependent from claim 20. Therefore, given the preamble of claim 16, and because claims 20 and 21 depend from claim 16, claims 20 and 21 appear to be drawn to polynucleotides comprising fragments of polynucleotides encoding SEQ ID NO: 2. In the

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previous Office action it was pointed out that the specification only teaches fragments of SEQ ID NO: 2 in the context of SEQ ID NO: 2 itself, or in the context of the specific fragment itself (consisting of the fragment).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 16 remains rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/57278 (Penn et al., 9 August 2001).

Applicants argue that the rejection is obviated by the amendments, because the claims no longer read on polynucleotides comprising nucleic acids comprising the sequence of SEQ ID NO: 5, 6 or 7. This is not found persuasive because the preamble of claim 16 is drawn to “an isolated nucleic acid molecule comprising a nucleotide sequence...”

Penn teaches nucleic acid molecules that comprise SEQ ID NO: 5, 6 or 7. Therefore, Penn teaches the claimed nucleic acid molecules.

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13. Claims 16, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession No. AAA97456 (CN1257923-A in database Geneseq, Gencore version 5.1.9)

Claims 16 and 20 are drawn to nucleic acid molecules where the polypeptide consists of an amino acid sequence with at least 98% sequence identity to SEQ ID NO: 2. Because of the phrase “consisting of an amino acid sequence”, the claims read on nucleotides encoding subsequences of SEQ ID NO: 2, and because of the preamble of claim 16, where claim 16 is drawn to “an isolated nucleic acid molecule comprising a nucleotide sequence...”, claims 16, 20 and 21 are drawn to sequences comprising polynucleotides encoding subsequences of SEQ ID NO: 2.

Accession No. AAA97456 comprises subsequences of SEQ ID NO: 2 (see alignment) and therefore teaches polynucleotides within the scope of the claims.

14. Claims 16, 20 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession No. AAS34856 (WO200155163-A in database Geneseq, Gencore version 5.1.9)

Claims 16 and 20 are drawn to nucleic acid molecules encoding polypeptides, where the polypeptides consist of an amino acid sequence with at least 98% sequence identity to SEQ ID NO: 2. Because of the phrase “consisting of an amino acid sequence”, the claims read on nucleotides encoding subsequences of SEQ ID NO: 2, and because of the preamble of claim 16, where claim 16 is drawn to “an isolated nucleic acid molecule comprising a nucleotide sequence...”, claims 16, 20 and 21 are drawn to sequences comprising polynucleotides encoding subsequences of SEQ ID NO: 2.



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Accession No. AAS34856 comprises subsequences of SEQ ID NO: 2 (see alignment) and therefore teaches polynucleotides within the scope of the claims.

15. Claims 16, 20, 21, 23, 34 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang (WO 01/53312 A1; publication date 26 July 2001; international filing date is 26 December 2000; pages 2-5, 27-32, 299, and 6443).

Tang discloses SEQ ID NO: 3567 (see page 6443) which is an amino acid sequence that encompasses or is the same as SEQ ID NOs: 10 and 22. Tang discloses polynucleotides encoding SEQ ID NO: 3567 (see pages 2-5, 27 and 299), methods of making polypeptides that require the use of host cells transfected with vectors comprising the encoding polynucleotides (see page 4, lines 4-10; page 29, lines 19-27). The claims are drawn to nucleic acids comprising polynucleotides encoding polypeptides consisting of amino acid sequences such as SEQ ID NO: 10, 14 and 22, vectors and host cells. Even though the claims contain the transitional phrase "consisting of" with respect to the polypeptide sequence, the claims are drawn to nucleic acid molecules that comprise polynucleotide sequences encoding those polypeptide sequences. Therefore, Tang teaches polynucleotides, vectors and host cells that are the same as that claimed.

### ***Conclusion***

No claim is allowed. Claims 17, 18 and 25 are objected for depending from a rejected claim.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official

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Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
March 7, 2007



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SUPERVISORY PATENT EXAMINER